Efficacy of Alveolar Ridge Preservation: A Randomized Controlled Trial

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APPENDIX

MATERIALS & METHODS

Sample Size Calculation

Data from a previous study in which the reported change in horizontal crestal ridge width for each group was normally distributed with standard deviations of 2.3mm for the control group and 0.9mm for the experimental group was used (Iasella et al. 2003). Our sample size calculation indicated that a minimum of 26 subjects per group would be required to reject the null hypothesis that the population means of the experimental and control groups are equal with probability (power) 80%, if the true difference between the experimental and control mean decrease at 14 weeks is 1.4mm. The Type I error probability associated with the test of this null hypothesis is 0.05.

Eligibility Criteria

Adult patients between 18 and 75 years of age who required the extraction of a tooth-bound single-rooted tooth, excluding mandibular incisors, were eligible to participate in the study. The exclusion criteria were as follows: 1) any periodontal attachment loss greater than 1 mm affecting the study tooth; 2) current smokers or former smokers who quit within 6 months prior to enrollment; 3) uncontrolled diabetes mellitus (defined as HbA1c>7.0); 4) severe hematologic disorders, such as hemophilia or leukemia; 5) liver or kidney failure; 6) any active local or systemic infections, as well as metabolic bone diseases, that may compromise normal wound healing; 7) currently receiving chemo- or radiotherapy or a history of radiotherapy in the head and neck area; 8) Any patients that were on concomitant medications that may affect the outcomes of the study; 9) Any subjects who were pregnant at the time of screening or trying to conceive; 10) mental disabilities that may interfere with reading, understanding and signing the informed consent and/or with following study-related instructions.

Recruitment

Patients who expressed an interest to participate in the study were pre-screened by phone. At the clinical screening examination, candidates were informed of the purpose and timeline of the study. All potential subjects were required to read, understand and sign the consent form, which included a thorough explanation of the study design, as well as expected benefits and possible risks of participating in the study.

Randomization

Following enrollment, patients were randomly assigned to one of two treatment modalities, using a computer-generated randomization list generated *a priori* by a team member not involved in the clinical procedures. Subjects allocated in the control group (EXT) received minimally invasive tooth extraction with no further treatment. Subjects allocated in the experimental group (ARP) received minimally invasive tooth extraction immediately followed by an alveolar ridge preservation procedure consisting of the combination of socket grafting using a particulate allograft material, and socket sealing using a dPTFE membrane.

Data Collection

A. Clinical Assessments

As described in the 'Clinical Procedures' section, mid-buccal KMW was measured by a calibrated examiner (G.A.) at baseline and at 14 weeks. Visual assessment of wound healing at 1, 4 and 14 weeks post-operatively was performed by the same examiner using a wound healing index (WHI), as reported in a previous publication (Hutton et al. 2018). The categories of this WHI are as follows: 1. Uneventful wound healing with no or minimal mucosal edema or erythema, and no suppuration or graft exposure; 2. Normal wound healing with slight to moderate mucosal edema, erythema, but no suppuration; and 3. Poor wound healing with severe mucosal edema, erythema and suppuration.

B. Linear Bone Measurements

A blinded examiner (M.R.) used the DICOM (Digital Imaging and Communication in Medicine) files from the CBCT scans obtained at baseline and at 14 weeks to make reproducible measurements of bucco-lingual ridge width, mid-buccal and mid-lingual height using a software package (InVivo v.5.3, Anatomage, San Jose, CA). Measurements were accomplished by using the same global image angulation and reproducible anatomic landmarks on the adjacent teeth, such as the cemento-enamel junction or crown margins, for maximum consistency between measurements. Horizontal ridge width measurements were made at approximately 3 mm apical to a line connecting the mid-facial zenith of the cemento-enamel junction (CEJ) of both teeth adjacent to the extraction site. This methodologic decision was driven by clinical relevance, since this is often the level at which the restorative platform of a standard bone level implant is placed (Figure 3).

C. Volumetric Assessments

C.1. Bone Volume Change

A separate blinded examiner (A.V.P. under 'Acknowledgements') performed the three-dimensional radiographic evaluations. DICOM files were processed and opened in a proprietary implant planning software (Simplant 16 Pro by Materialise, Dentsply Implants, Waltham, MA) that allows for the selection of

a bone volume of interest (VOI) using constant thresholds. The six boundaries of the VOI were a plane over the crestal bone, a plane over the root apex, a plane over the most external aspect of the buccal and lingual bony plates and an extension in both the mesial and distal direction of approximately 2 to 3 mm, for reference purposes to facilitate reliable comparative assessments, as shown in Video S1. The same segmentation settings were used for both the baseline and 14-week DICOM files. The total volume of the VOIs was quantified using Simplant Pro 16 in order to calculate the percentual loss of volume that occurred over the 14 weeks by subtraction analysis.

C.2. Soft Tissue Volume Change

Stone casts were made from the impressions obtained at baseline and 14 weeks post-operatively (Microstone, Whip Mix Corp., Louisville, KY, USA). Models were scanned using a 3D scanner (3M LavaSoft Scanner, 3M, St. Paul, MN, USA) to obtain stereolithographic (STL) digital files that were analyzed by a blinded examiner (C.L.N.) using a software package (Geomagic Studio, 3D Systems, Rock Hill, SC, USA). First, for each subject, the baseline and 14-week scans were superimposed using the "Manual Registration" function ("Global Registration", which superimposes scans automatically, was found to be inaccurate). Second, both volumes were simultaneously trimmed by four planes: a coronal plane over the most coronal point of the mesial and distal papillae, an apical plane at the base of the vestibulum and two interproximal planes that contacted with the most proximal point of the adjacent teeth. Third, the 14-week volumes were measured from the zenith-point of the mid-buccal mucosa, to a point 4 mm superior. Data from subjects whose impressions did not reach at least 4mm in this vertical dimension were excluded from the analysis. Fourth, the superimposed scans were then simultaneously trimmed horizontally at the apical mark selected in the previous step. Fifth, all supragingival tooth structures in the baseline scan were selectively trimmed from the final volume, for precise comparisons. Sixth, the open/trimmed surfaces of the scans were digitally filled in to generate VOIs. Lastly, the VOIs were measured separately, using the “compute volume” function, to subtract the 14-week VOI from the baseline VOI and subsequently generate a percentage of volume change through time (Appendix figure 1).

D. Need for Additional Bone Augmentation for Implant Placement

An experienced clinician (G.A.) used a software package (InVivo v.5.3, Anatomage, San Jose, CA) to digitally plan implant placement in prosthetically favorable location at each edentulous site. A bone level implant with a diameter of 4.0 mm and a length of 9.0 mm was chosen as the standard for all sites, except for maxillary lateral incisors, where 3.5mm diameter and 9.0 mm length implants were used. Additional bone augmentation prior to or at time of placement was deemed to be necessary if a minimum of 1 mm of circumferential bone support was not observed around the whole implant (Figure 3).

E. PROMs

Subjects were asked by a study team member (L.T. under 'Acknowledgements') to rate self-reported postoperative discomfort at 1, 4 and 14 weeks post-operatively, and overall satisfaction upon study completion (at 14 weeks) using a 100-point visual analog scale (VAS). This was done prior to the clinical examination to minimize observer effect bias.

Statistical Analyses

Mean and standard deviation for normally distributed variables or median and interquartile range for non-normally distributed variables were calculated for the outcomes assessed in the two groups, with normality assessed using the Shapiro-Wilk test.

For the clinical measurement of KMW and linear radiographic measurement of HRW, which were normally distributed, linear mixed model analysis was used to compare mean change between the treatment groups (EXT or ARP). The fixed effects in the mixed model included treatment group (EXT / ARP), time (Baseline / 14 weeks), and treatment-time interaction, with the test for treatment-time interaction effect corresponding to the test comparing mean change between the test and the control group. In addition, test of mean contrast based on the fitted mixed model was performed to test for change over time within each group, and also compare between the groups at each time. P-values for these tests were adjusted using Bonferroni's method, i.e. adjusted p-value=2 (unadjusted p-value) for testing for change within each group; and for comparing between the experimental and control group at each time. The outcome measures that did not have a normal distribution (BSTW, BRH and LRH) were compared between treatment groups using Wilcoxon rank-sum test, with within group change assessed using Wilcoxon signed rank test. P-values for these tests were adjusted using Bonferroni's method, i.e. adjusted p-value=2 (unadjusted p-value) for testing for change within each group; and for comparing between the experimental and control group at each time. Linear regression analyses were performed to determine the effect of baseline clinical parameters (mid-buccal and mid-lingual alveolar bone and gingival thickness, and KMW) on ΔBV. The relationship between buccal bone thickness and ΔBV was further explored using multivariate logistic regression to determine what threshold of buccal bone thickness would be associated with at most 10% of bone volume loss. Other statistical tests used included two-sample t-test to compare mean ΔBV, and Pearson Chi-square test to compare the proportion of patients requiring additional bone augmentation at the time of or prior to implant placement between the two groups. All statistical analyses were performed using SAS (version 9.4), with a p-value of $< .05$ considered statistically significant.

DISCUSSION

Therapeutic rationale

The main indication of ARP in contemporary clinical practice is to minimize post-extraction dimensional changes of the alveolar ridge in order to facilitate tooth replacement therapy. Numerous ARP strategies, involving the use of different biomaterials applied alone or in combination, have been proposed in the literature (Avila-Ortiz et al. 2019). A recent evidence-based expert consensus acknowledged that, although no specific ARP approach has been proven to be patently superior, the application of a bone grafting material to fill the fresh extraction socket and sealing the socket orifice using an autogenous or exogenous barrier is strongly recommended (Tonetti et al. 2019).

In spite of the robust clinical evidence supporting its efficacy, the mechanism by which ARP via filling the socket with a bone grafting material and sealing the orifice with a barrier element contribute to the maintenance of the alveolar ridge architecture after tooth extraction has not been fully elucidated. Nonetheless, a plausible explanation has been previously proposed (Avila-Ortiz and Zadeh 2019). The bone grafting material that occupies the socket space in lieu of a blood clot is believed to induce a slower healing pattern that translates into a phenomenon of delayed bone turnover within the socket, which ultimately contributes to preserving the alveolar bone architecture. Additionally, occlusion of the socket orifice using a barrier is performed to limit or impede soft tissue downgrowth into the bone compartment through the inhibition of rapid epithelial and fibroblast cell proliferation. The presence of a barrier membrane over the socket during early stages of healing may also contribute to minimize the extravasation of grafting material, as well as preventing the infiltration of microorganisms and debris from the oral cavity.

In this study, ARP therapy consisted of a combination of socket grafting with a particulate bone allograft (70% FDBA and 30% DFDBA) and socket sealing with a non-absorbable (dPTFE) synthetic barrier. The selection of a combined allograft can be justified by the specific properties of each material. DFBDA, which was used in a smaller proportion, is a rapidly absorbable material which allows for adequate early angiogenesis and stimulation of pluripotential cell migration and differentiation. FDBA, is a mineralized material that provides a slow-absorbing scaffold conducive to new bone formation. Further, the rationale for the use of a fully occlusive dPTFE barrier was to leverage on effective compartmentalization of the bone and overlying soft tissues, with the purpose of creating a favorable healing environment for maximum ridge preservation. In all experimental sites, the dPTFE barrier was gently removed at the 4-week visit, because at that time point, in normal conditions of healing, the proliferative phase, which is characterized by active woven bone formation in the socket, would be ongoing and, therefore, the barrier effect would no longer be necessary. Alveolar ridge maturation typically culminates between 12 and 16 weeks after tooth

extraction (Avila-Ortiz and Zadeh 2019), which justifies why the study completion was set at 14 weeks from baseline.

Agreements and Disagreements with Existing Evidence

The main findings of this randomized controlled trial are in accordance with the existing body of high-level evidence (Tonetti et al. 2019). However, the magnitude of the effect of ARP as compared to unassisted socket healing in terms of horizontal linear bone changes is smaller than what has been generally reported in the literature. This divergence can be primarily explained by methodological differences. Horizontal ridge width measurements were made at a height of approximately 3 mm respective to a line connecting the mid-facial zenith of the CEJ of both teeth adjacent to the extraction site. This decision was made on the basis of clinical relevance, as that is typically the vertical level at which the implant platform would be placed, especially in esthetic sites, to allow for a favorable emergence profile. As observed in this and in previous studies (Chappuis et al. 2015; Misawa et al. 2016), bone resorption is more pronounced at the most coronal and facial aspect of the alveolar ridge. Hence, measurements made at a more apical level than what most previous studies have reported can explain the discrepancy in observed results.

Only a handful of clinical trials in the topic of alveolar ridge preservation have reported ΔSTV (El Shazley et al. 2016; Hong et al. 2019; Sbordone et al. 2017; Zadeh et al. 2016) and ΔBV (Barone et al. 2017; Barone et al. 2016; Pang et al. 2014). Our findings are generally in agreement with the existing literature. This confirmatory evidence is reinforcing and also raises the question as to whether volumetric analysis should be considered the new gold standard method for the assessment of dimensional changes following intraoral surgical interventions given its higher reproducibility, precision and clinical relevance, as compared to linear radiographic or direct intraoral measurements.

Likewise, although the available evidence regarding PROMs after ARP is scarce and pertains to the use of blood-derived products (Alissa et al. 2010; Temmerman et al. 2016), which is not a comparable approach to that followed in our study, our findings regarding perceived discomfort at different time points and overall satisfaction are comparable to those reported in the existing literature.

Limitations

Assessment of ΔSTV could not be performed for all 53 subjects who completed the study due to limitations pertaining to the vestibular extent of the impressions obtained at baseline and 14 weeks, which is dependent on the specific soft tissue anatomy of each subject. Nevertheless, ΔSTV could be calculated using the data from 13 patients in each group.

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Appendix table 1. Schedule of Events

Visit	1	2	3	4	5
Description	Screening	Baseline	Postop	Follow-up	Final Visit
Chronology (Time Window)	< 8 weeks prior to Baseline	Time Zero	Baseline + 1 week (±2 days)	Baseline + 4 weeks (±3 days)	Baseline + 14 weeks (±7 days)
Informed Consent	X				
Verification of Eligibility Criteria	X				
Medical & Dental History Update	X	X	X	X	X
CBCT Scan		X			X
PVS Impression		X			X
PROMs			X	X	X
Wound Healing Index			X	X	X
Assessment of Adverse Events		X	X	X	X
Approximate Visit Length	60 minutes	60 to 90 minutes	20 minutes	20 minutes	20 minutes

CBCT, cone beam computed tomographic; PROMs, patient-reported outcome measures; PVS, polyvinyl siloxane.

Appendix table 2. Baseline clinical parameters from both groups.

Baseline Parameters (all in mm)	Extraction Alone Group (Mean ± SD)	Alveolar Ridge Preservation Group (Mean ± SD)
Keratinized mucosa width	3.81 ± 1.27	4.31 ± 1.69
Buccal bone thickness	0.71 ± 0.31	0.98 ± 0.35
Lingual bone thickness	1.00 ± 0.36	0.87 ± 0.24
Buccal mucosa thickness	0.49 ± 0.2	0.43 ± 0.13
Lingual mucosa thickness	0.83 ± 0.33	0.84 ± 0.36
Radiographic buccolingual width	9.26 ± 0.37	9.36 ± 0.38

Appendix table 3. Tooth site distribution per group.

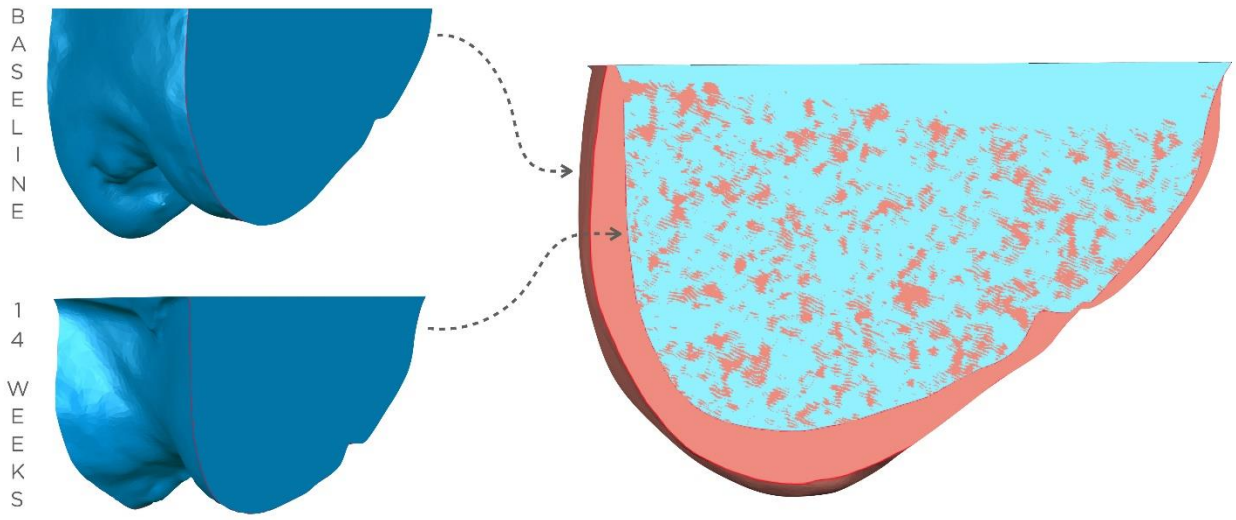
TOOTH TYPE	Extraction Alone Group	Alveolar Ridge Preservation Group
Maxillary Central Incisor	3	2
Maxillary Lateral Incisor	5	5
Maxillary Canine	2	2
Mandibular Canine	0	1
Maxillary Pre-Molar	13	11
Mandibular Pre-Molar	4	5

Appendix table 4. Mean wound healing index values at different time points after tooth extraction.

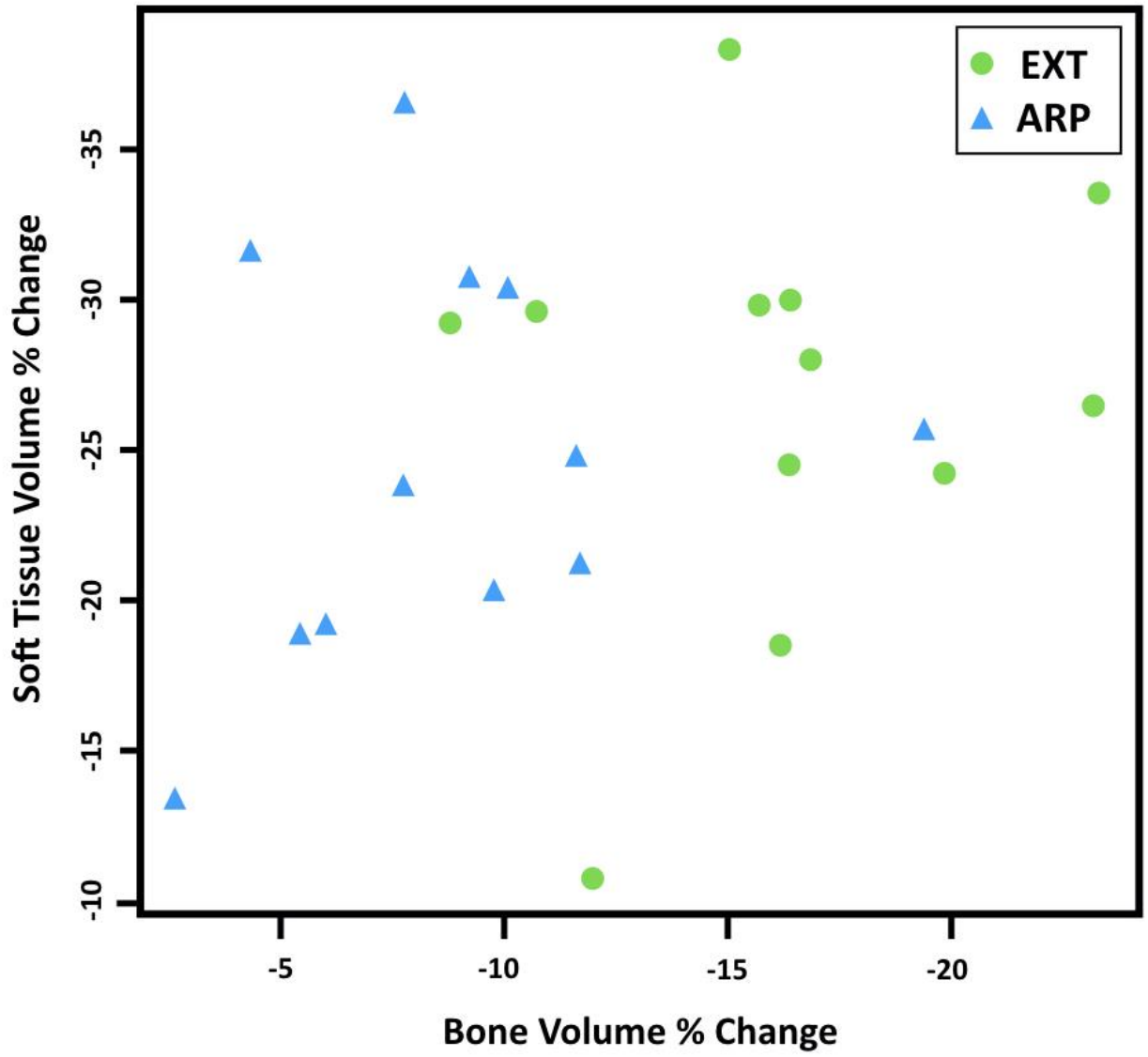
Follow-up Time Point	Extraction Alone Group (Mean ± SD)	Alveolar Ridge Preservation Group (Mean ± SD)
1 week	2.04 ± 0.44	2.04 ± 0.2
4 weeks	1.33 ± 0.55	1.77 ± 0.43
14 weeks	1 ± 0	1 ± 0

Appendix table 5. Median perceived discomfort values (0 minimum to 100 maximum) at different time points after tooth extraction.

Follow-up Time Point	Extraction Alone Group (Median ± IQR)	Alveolar Ridge Preservation Group (Median ± IQR)	
1 week	6 (0-10)	6 (1-13)	p = 0.419
4 weeks	0 (0-3)	2 (0-3)	p = 0.531
14 weeks	3 (0-13)	5 (1-11)	p = 0.383



Appendix figure 1. Superimposition of VOIs obtained from segmentation of STL files representing the soft tissue contour of the ridge at baseline and 14 weeks after tooth extraction.

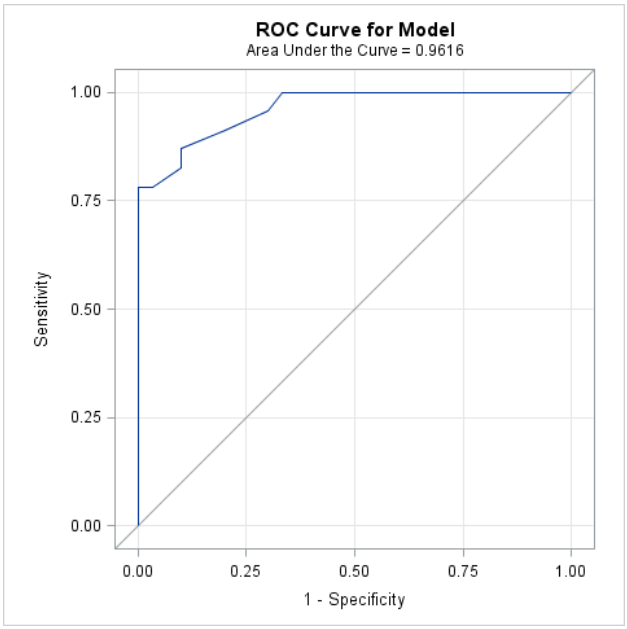


Appendix figure 2. Scatter plot illustrating the analysis of the correlation between ΔSTV and ΔB.

Logistic regression of ≤10% volumetric ridge reduction with treatment group and buccal bone thickness as independent variables

Analysis of Maximum Likelihood Estimates						
Parameter		DF	Estimate	Standard Error	Wald Chi-Square	p-value
Intercept		1	-8.4513	2.5549	10.9421	0.0009
txt_group	Graft (vs. control)	1	3.4218	1.1733	8.5054	0.0035
baseline_d1		1	7.5078	2.4287	9.5560	0.0020

Odds Ratio (OR) Estimates and Wald Confidence Intervals			
Effect	OR	95% Confidence Limits	
txt_group (Graft vs control)	30.63	3.07	305.36
baseline_d1 (per +0.1)	2.12	1.32	3.41



Prob Level	Correct		Incorrect		Percentages				
	Event	Non-Event	Event	Non-Event	Correct	Sensitivity	Specificity	False POS	False NEG
0.000	23	0	30	0	43.4	100.0	0.0	56.6	.
0.020	23	19	11	0	79.2	100.0	63.3	32.4	0.0
0.040	23	19	11	0	79.2	100.0	63.3	32.4	0.0
0.060	23	19	11	0	79.2	100.0	63.3	32.4	0.0
0.080	23	20	10	0	81.1	100.0	66.7	30.3	0.0
0.100	22	20	10	1	79.2	95.7	66.7	31.3	4.8
0.120	21	20	10	2	77.4	91.3	66.7	32.3	9.1
0.140	21	20	10	2	77.4	91.3	66.7	32.3	9.1
0.160	21	20	10	2	77.4	91.3	66.7	32.3	9.1
0.180	21	21	9	2	79.2	91.3	70.0	30.0	8.7
0.200	20	21	9	3	77.4	87.0	70.0	31.0	12.5
0.220	20	21	9	3	77.4	87.0	70.0	31.0	12.5
0.240	20	21	9	3	77.4	87.0	70.0	31.0	12.5
0.260	20	24	6	3	83.0	87.0	80.0	23.1	11.1
0.280	20	24	6	3	83.0	87.0	80.0	23.1	11.1
0.300	20	24	6	3	83.0	87.0	80.0	23.1	11.1
0.320	20	24	6	3	83.0	87.0	80.0	23.1	11.1
0.340	20	27	3	3	88.7	87.0	90.0	13.0	10.0
0.360	20	27	3	3	88.7	87.0	90.0	13.0	10.0
0.380	20	27	3	3	88.7	87.0	90.0	13.0	10.0
0.400	20	27	3	3	88.7	87.0	90.0	13.0	10.0
0.420	20	27	3	3	88.7	87.0	90.0	13.0	10.0
0.440	20	27	3	3	88.7	87.0	90.0	13.0	10.0
0.460	20	27	3	3	88.7	87.0	90.0	13.0	10.0
0.480	20	27	3	3	88.7	87.0	90.0	13.0	10.0
0.500	20	27	3	3	88.7	87.0	90.0	13.0	10.0
0.520	20	27	3	3	88.7	87.0	90.0	13.0	10.0
0.540	20	27	3	3	88.7	87.0	90.0	13.0	10.0
0.560	19	27	3	4	86.8	82.6	90.0	13.6	12.9
0.580	19	27	3	4	86.8	82.6	90.0	13.6	12.9
0.600	19	27	3	4	86.8	82.6	90.0	13.6	12.9
0.620	19	27	3	4	86.8	82.6	90.0	13.6	12.9
0.640	19	27	3	4	86.8	82.6	90.0	13.6	12.9
0.660	19	27	3	4	86.8	82.6	90.0	13.6	12.9
0.680	19	27	3	4	86.8	82.6	90.0	13.6	12.9
0.700	18	27	3	5	84.9	78.3	90.0	14.3	15.6
0.720	18	27	3	5	84.9	78.3	90.0	14.3	15.6
0.740	18	27	3	5	84.9	78.3	90.0	14.3	15.6
0.760	18	27	3	5	84.9	78.3	90.0	14.3	15.6
0.780	18	27	3	5	84.9	78.3	90.0	14.3	15.6
0.800	18	29	1	5	88.7	78.3	96.7	5.3	14.7
0.820	18	29	1	5	88.7	78.3	96.7	5.3	14.7
0.840	13	29	1	10	79.2	56.5	96.7	7.1	25.6
0.860	13	29	1	10	79.2	56.5	96.7	7.1	25.6
0.880	13	29	1	10	79.2	56.5	96.7	7.1	25.6
0.900	13	29	1	10	79.2	56.5	96.7	7.1	25.6
0.920	10	30	0	13	75.5	43.5	100.0	0.0	30.2
0.940	10	30	0	13	75.5	43.5	100.0	0.0	30.2
0.960	10	30	0	13	75.5	43.5	100.0	0.0	30.2
0.980	9	30	0	14	73.6	39.1	100.0	0.0	31.8
1.000	0	30	0	23	56.6	0.0	100.0	.	43.4

Based on the fitted logistic regression model parameter estimates, the probability cut-off of 0.34 for the outcome of $\leq$10% volumetric reduction corresponds to a buccal plate thickness (d1) cut-off of >0.6 after ARP, and >1.0 after EXT.